

2020 03 11

2020 12 11

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Ustekinumab Injection(Intravenous Infusion)

Wusinu Dankang Zhusheye Jingmai Shuzhu

L-

L-

80 L-

130mg/26ml/

8 90mg 12 90mg IV 1

1

	^a 130 mg
260 mg	2
390 mg	3
	4

a 6 mg/kg

8

12 1 8 1

8 12 1

16 8 1 16

/

8 1

1. 1.
1 26mL 130mg
2. 9 mg/mL 0.9%
26 mL
2 3 78 mL 4 104 mL
3. 26 mL
4.
1 8
6. 0.2
7.
8.

1.38
 0.03
 829
 27
 0.03
 11
 0.99
 3.2
 1.0
 0.6
 0.91
 0.02
 178
 829
 1
 0.26
 0.12
 100
 100

RPLS
RPLS

RPLS

12.4%
3%

/

CT

T

-

T cell enzyme-linked immune-spot assay

T-SPOT.TB

T

Quanti FERON-TB Gold QFT-G

IL-12/IL-23

BCG

IL-12/IL-23

60

PUVA

[BCG]

2

MTX

1-3

/

—

18

—————

III

100

90%

MTX

NSAID

6-

IL-12 IL-23

10 ng/ml IL-12 / IL-23
CYP1A2 2B6 2C9 2C19 2D6 3A4

IL-1 IL-6 IL-10 TNF IFN
IL-12 IL-23

MTX

6 mg/kg

CDAI

UNITI-1	UNITI-2	44	8	IM-
UNITI		1409	UNITI-1 n=769	UNITI-2 n=640
		6	CDAI	
			8	
			0	

6 mg/kg 1 130 mg

UNITI-1 48%

1 2 3

29.1% 36.4% 69.4%

UNITI-2

68.6%

31.4%

UNITI-1 UNITI-2

3

8

130 mg

		UNITI-1*		UNITI-2**	
		N=247	N=249	N=209	N=209
8		18 (7.3%)	^a	41 (19.6%)	84 (40.2%) ^a
6	100		84 (33.7%) ^b	60 (28.7%)	^a
8	100		94 (37.8%) ^a	67 (32.1%)	^a
70	3	67 (27.1%)	101 (40.6%) ^b	66 (31.6%)	^a
70	6		109 (43.8%) ^b	81 (38.8%)	^a

CDAI

CDAI

100

70

*

**

^a p 0.001

^b p 0.01

IM-UNITI

UNITI-1

UNITI-2

8

100

388

90 mg

8

90 mg

12

44

44

6

6 IM-UNITI

44

	* N=131 [†]	90 mg 8 1 N=128 [†]	90 mg 12 1 N=129 [†]
	36%	a	49% ^b
	44%	b	b
	30%	47% ^a	43% ^c
	46% (36/79)	a	
CRD3002	44% (31/70) [‡]	c	
		c	
CRD3001	26% (16/61) [§]		

	CDAI	CDAI	100
*			
†		100	
‡			
§	/		
a	p 0.01		
b	p		
c	p		
	IM-UNITI 29/129	12 1	
		8 1	
	CDAI 220	CDAI	100
41.4%	16		
	UNITI-1 UNITI-2	8	
	476	IM-UNITI	
	90 mg	8	
	8		44
	68.1%		
	131	90 mg	
	8 1		
24		70.6%	
	16	39.2%	
	IM-UNITI	44	
		TNF	
		92	

SES-CD
 /
 /
 8
 SES-CD n=97 = -0.7 p=0.012 = -2.8

44
 8.8% n=26 80%

36
 UNITI-1 IBDQ SF-36
 UNITI-2 IBDQ SF-
 UNITI-2 SF-36
 44 IM-UNITI

p40
 IL-12 IL-23
 IL-12 IL-23
 CD⁴⁺T
 IL-12R
 IL-12 IL-23
 IL-12 IL-23 p40

mg/kg

IL-12/IL-23p40

1 - 2

1 100

90mg 4 100

- 33 2

1 100 6 1

12 IL-12/IL-23 p40 IL-

IL-12 IL-23 IL-12 IL-12/IL-23 p40

26 10 26

1

90 mg

mg

90 mg

T_{max}

T_{max}

V_z

ml/kg

CL

/kg

$t_{1/2}$

3

CL/F

V/F

$t_{1/2}$

3

CL/F

C_{max}

AUC

-

0	4			12			
		28			90 mg	12	
	126.1µg/ml	8			90mg		8
12	1		2				
90mg		8	1	12	1		
1.97µg/ml	2.24µg/ml	0.61µg/ml		0.76µg/ml	90mg	12	1
		90mg	8	1			

			100 kg	CL/F	
100 kg			100 kg	V/F	100
kg	37%	90 mg		100 kg	
		mg		100 kg	

CL/F V/F

IL-12 IL-23
10 ng/ml IL-12 / IL-23
CYP1A2 2B6 2C9 2C19 2D6 3A4

I

1 /

36

JS

Janssen-Cilag International NV

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Cilag AG

710304

400 888 9988

<http://www.xian-janssen.com.cn>